

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

**MASSIE REA, III,
Individually and as Trustee for The
Next of Kin of Massie Rea, Jr., Decedent,**

Case No.: 07-CV-2232-PJS/RLE

Plaintiff,

v.

**PFIZER INC., a Delaware Corporation;
PHARMACIA CORPORATION, a
Delaware Corporation; and G.D. SEARLE
LLC, a Delaware Corporation,**

**DEFENDANTS PFIZER INC.,
PHARMACIA CORPORATION,
AND G.D. SEARLE, LLC'S
ORIGINAL ANSWER TO
PLAINTIFF'S COMPLAINT**

Defendants.

Jury Trial Demanded

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COME Defendants Pfizer Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia") and G.D. Searle LLC ("Searle") and file this their Original Answer to Plaintiff's Original Complaint ("Complaint"), and would respectfully show the Court as follows:

**I.
PRELIMINARY STATEMENT**

The Complaint does not state in sufficient detail when Decedent Massie Rea, Jr., ("Decedent") was prescribed or used Bextra®. Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Decedent was prescribed and used Bextra®.

II.
ORIGINAL ANSWER

Response to Allegations Regarding Parties

1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but deny that Plaintiff is entitled to any relief or damages. Defendants state that the potential effects of Bextra® (valdecoxib) were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's and Decedent's citizenship, whether Decedent used Bextra®, and whether Plaintiff has standing to bring this suit, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare

providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this Paragraph of the Complaint.

Response to Allegations Regarding Jurisdiction and Venue

6. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations concerning the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiff claims that the amount in controversy exceeds \$75,000, exclusive of interests and costs. Defendants deny that Bextra® caused Plaintiff or Decedent injury or damage and deny the remaining allegations in this paragraph of the Complaint.

7. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations concerning the Plaintiff's citizenship and the amount in controversy and, therefore, deny the same. However, Defendants admit that Plaintiff claims that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of interests and costs. .

8. Defendant is without knowledge or information sufficient to form a belief as to the judicial district in which the asserted claims allegedly arose, and, therefore deny that venue is proper in this district pursuant to 28 U.S.C. § 1391. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra is dangerous and deny the remaining allegations in this paragraph of the Complaint.

9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Multidistrict Litigation

10. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that this case should be transferred to In re: Bextra and Celebrex Marketing Sales Prac. and Pro. Liab.

Lit., MDL-1699, assigned to the Honorable Charles R. Bryer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

Response to Factual Allegations

11. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Decedents' medical condition and whether Decedent used Bextra® and, therefore, deny the same. Defendants deny that Bextra® caused Plaintiff or Decedent injury or damage and deny the remaining allegations in this paragraph of the Complaint.

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® caused Plaintiff or Decedent injury or damage and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

15. Defendants admit that Bextra® was expected to reach consumers without substantial change from the time of sale. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and,

therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

16. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny remaining the allegations in this paragraph of the Complaint.

17. The allegations in this paragraph of the Complaint regarding aspirin, naproxen, and ibuprofen are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the such allegations. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. With regard to allegations directed to Bextra®, Defendants state that, as stated in the FDA-approved labeling for Bextra®, “[t]he mechanism of action is believed to be due to the inhibition of prostaglandin synthesis primarily through inhibition of cyclooxygenase-2 (COX-2). At therapeutic plasma concentrations in humans valdecoxib does not inhibit cyclooxygenase-1 (COX-1).” Defendants deny the remaining allegations in this paragraph of the Complaint.

18. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

19. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this

paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

20. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

21. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

22. The allegations in this paragraph of the Complaint regarding “other pharmaceutical companies” are not directed toward Defendants, and, therefore, no response is required. Plaintiff fails to provide the proper context for the remaining allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

23. Defendants state that Plaintiff’s allegations regarding “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

24. Defendants admit that Celebrex® was launched in the United States in February 1999. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain

periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

25. Defendants admit that the New Drug Application for Bextra® was filed with the FDA on January 15, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

26. Defendants admit that Bextra® was approved by the FDA on November 16, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

27. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

28. Defendants admit that Bextra® was approved by the FDA on November 16, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

29. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

30. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

31. The allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

32. Defendants admit that the New Drug Application for Bextra® was filed with the FDA on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November 16, 2001. Defendants deny the remaining allegations in this paragraph of the Complaint.

33. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

34. Defendants refer to the December 9, 2004 FDA Talk Paper for Bextra®, which speaks for itself, and any attempt to characterize it is denied. Defendants deny the allegations in this paragraph of the Complaint.

35. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

36. Plaintiffs fail to provide the proper context for the allegations concerning the “post-drug approval meta-analysis study” in this paragraph of the Complaint. Defendants are therefore without sufficient information to confirm or deny such allegations and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

37. The allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is necessary. Should a response be deemed necessary, Defendants

state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. The allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is necessary. Should a response be deemed necessary, Defendants admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee was held on February 16-18, 2005. Defendants state that the referenced testimony speaks for itself and respectfully refer the Court to the testimony for its actual language and text. Any attempt to characterize the testimony is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

40. Defendants refer to the Alert for Healthcare Professionals issued by the FDA on April 7, 2005, which speaks for itself, and any attempt to characterize it is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

41. Defendants refer to the Alert for Healthcare Professionals issued by the FDA on April 7, 2005, which speaks for itself, and any attempt to characterize it is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

42. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this paragraph of the Complaint.

43. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

44. The allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

45. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

46. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

47. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

48. Defendants deny the allegations in this paragraph of the Complaint.

49. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and

packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the allegations in this paragraph of the Complaint.

50. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

51. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in

the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

52. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

53. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are

adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

54. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

55. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

56. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

57. Defendants deny the allegations in this paragraph of the Complaint.

58. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market as of April 7, 2005. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

59. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which

was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

60. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

61. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

62. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

63. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and

packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

64. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

65. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding and whether Decedent used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Negligence

66. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

67. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

68. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

69. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

70. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants

are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

71. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

72. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

73. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

74. Defendants deny that Bextra® caused Plaintiff or Decedent injury or damage and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Liability

75. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

76. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants admit that Bextra® was expected to reach consumers without substantial change in the condition from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

77. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

78. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

79. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

80. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

81. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

82. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

83. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

84. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

85. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

86. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

87. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® is defective and deny the remaining allegations in this paragraph of the Complaint.

88. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

89. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action: Breach of Express Warranty

90. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

91. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which

was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

92. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint, including all subparts.

93. Defendants deny the allegations in this paragraph of the Complaint.

94. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

95. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny any wrongful conduct the remaining allegations in this paragraph of the Complaint.

96. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

97. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

98. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fourth Cause of Action: Breach of Implied Warranty

99. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

100. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

101. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

102. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid

arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

103. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

104. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants state that Bextra® was expected to reach consumers without substantial change in the condition from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

105. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in paragraph 108 of Plaintiffs' Complaint.

106. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

107. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment

108. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

109. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state

that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

110. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

111. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

112. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

113. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants

deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

114. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

115. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

116. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

117. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

118. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

119. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

120. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

121. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Unjust Enrichment

122. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

123. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

124. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

125. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

126. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

127. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

128. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Seventh Cause of Action: Wrongful Death

129. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

130. This paragraph of the Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Defendants have insufficient information to form a belief as to the truth of the allegations in this paragraph of the Complaint, and therefore deny the same.

131. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

132. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

133. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer for Relief

Defendants deny the allegations contained in the unnumbered paragraph headed "Prayer for Relief," including all subparts.

**III.
GENERAL DENIAL**

Defendants deny the allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

**IV.
AFFIRMATIVE DEFENSES**

Defendants reserve the right to rely upon any of the following or additional defenses to

claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is plead in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. Plaintiff's claims against Defendants are barred to the extent Plaintiff and/or Decedent was contributorily negligent, actively negligent or otherwise failed to mitigate her damages, and any recovery by Plaintiff should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants is not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff and Decedent were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to the Plaintiff or Decedent.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Decedent's treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff's and Decedent's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Bextra® after the product left the control of Defendants and any

liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff's and Decedent's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Nineteenth Defense

19. Plaintiff and Decedent knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and Article I, § 17 of the Constitution of the State of Minnesota, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Minnesota law.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff and Decedent failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of Minnesota. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of

punitive-damages based on out-of state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff or Decedent; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff or Decedent and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff and Decedent have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's and Decedent's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff and Decedent, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff or Decedent.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff and Decedent did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Decedent would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the

common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff’s claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA’s implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff’s claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff’s misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants reserve the right to supplement their assertion of defenses as it continues with its factual investigation of Plaintiff’s claims.

V.

JURY DEMAND

Defendants hereby demand a trial by jury.

VI.
PRAYER

WHEREFORE, Defendants pray that Plaintiff take nothing by their suit; that Defendants be discharged with their costs expended in this matter, and for such other and further relief to which it may be justly entitled.

Dated: May 29, 2007.

FAEGRE & BENSON LLP

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